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510(k) SUMMARY

[Submitted pursuant to 21 CFR 807.92(a). All data included in this document are accurate and complete to the best of DSC's knowledge.]

1. Submitter Information

Submitter:	Direx Systems Corporation 960 Turnpike Street Canton, MA 02021
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Contact Person	Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade/Proprietary Name:	Duet Magna
Common/Usual Name:	Extracorporeal Shock Wave Lithotripter (ESWL)
Regulation Number:	21 CFR 876.5990
Regulatory Class:	Class II (special controls)
Product code:	78 LNS
Panel:	Gastroenterology and Urology

3. Predicate Devices

Tripter X – 1 Compact Duet (Direx Systems Corp) (K023535)

Tripter X – 1 Compact Duet (Direx Systems Corp) (K041582)

Integra (Direx Systems Corp) K053640)

4. Intended Use:

The DUET MAGNA is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and upper ureter.

5. Description

The device is a transportable Electromagnetic Extracorporeal Shock Wave

Lithotripter incorporating a Shock Wave Generator (SWAG), a Motorized Floating Treatment Table (MFT), and a Control subsystem.

Also incorporated are interfaces for ECG synchronization, fluoroscopic imaging devices and sonographic imaging devices.

The SWAG incorporates two stationary reflector-based electromagnetic transducers (Bottom and Top). Software control enables separate operation of the transducers in any one of three operating modes: "B" (Bottom only), "T" (Top only), "A" (B and T operate alternatively in a cyclic fashion, such that the time difference between the B and T pulses equals the time difference between the T and B pulses.

6. Performance Testing

The *DUET MAGNA* Lithotripter was tested according to the following standards:

- IEC 60601-1 (1988) +A1 (1991) +A2 (1995)
- IEC 60601-1-1 (2000)
- IEC 60601-1-2 (2001)
- IEC 60601-1-3 (1994)
- IEC 60601-2-7 (1998)
- IEC 606001-2-36 (1997)
- IEC 61846 (1998)
- IEC 60601-2-38 (1996)
- ANSI/ AAMI/ ISO 10993– 1 (1998)
- CISPR 11 (1997) + A1 (1999) class B
- IEC 60601-1-4 (2000)
- Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; August 9, 2000

6. Substantial Equivalence

The intended use of **Duet Magna** is respectively similar to those of the predicate devices. The device is a modification of **Tripter Compact Duet** and is functionally similar to **Tripter Compact Duet**, except for shockwave generation that is similar to that of Integra. Furthermore, the Duet Magna has been tested and been found to conform, as do the predicate devices, to FDA recognized standards, including electrical safety testing per IEC 60601-1, EMC testing per IEC 60601-1-2, localization accuracy testing and road testing per the lithotripter special control guidance document. Based on an analysis of similarities and differences, we believe that **Duet Magna** is substantially equivalent to its predicate devices without raising new safety and/or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Larisa Gershtein
QA Manager
Direx Systems Corp.
437 Turnpike Street
CANTON MA 02021

MAR - 1 2012

Re: K111947
Trade/Device Name: DUET MAGNA
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal shock wave Lithotripter
Regulatory Class: II
Product Code: LNS
Dated: January 30, 2012
Received: February 3, 2012

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111947

Device Name: DUET MAGNA

Indications for Use:

DUET MAGNA is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and upper ureter.

Prescription Use - Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111947